REMARKS

Claims 1-28 and 36-50 were cancelled in a preliminary amendment. Claims 31-35 were cancelled during prosecution of the application. Claim 30 was cancelled in an Amendment under 37 C.F.R. 1.116. Claim 29 remains pending in the application and is currently amended. New dependent claims 51 and 52 have been added. Support for the new claims is found on page 26, lines 30-35.

35 U.S.C. §112, Second Paragraph

A. Claim 29 was rejected under 35 U.S.C. §112, second paragraph as being vague and indefinite for lacking an antecedent basis for producing the two antibodies that are required in step (e).

Claim 29 is amended to clarify the claim to a method for producing a passive immunity vaccine against *Sarcocystis neurona* in horses. The method comprises: (a) providing *Sarcocystis neurona* 16 (+/-4) kDa antigen and *Sarcocystis neurona* 30 (+/-4) kDa antigen, as determined by SDS polyacrylamide gel electrophoresis; (b) immunizing one or more mammals with the *Sarcocystis neurona* 16 (+/-4) kDa

antigen and the *Sarcocystis neurona* 30 (+/-4) kDa antigen, in admixture with an adjuvant, to produce antibodies against the *Sarcocystis neurona* 16 kDa +/-4 antigen and antibodies against the *Sarcocystis neurona* 30 kDa +/-4 antigen; (c) removing serum from the one or more immunized mammals; (d) isolating from the serum from the one or more immunized mammals the antibodies against the *Sarcocystis neurona* 16 kDa +/-4 antigen and the antibodies against the *Sarcocystis neurona* 30 kDa +/-4 antigen; and (e) providing the antibodies to the 16 (+/-4) kDa antigen and antibodies to the 30 kDa (+/-4) antigen, isolated in step (d), together as the passive immunity vaccine against *Sarcocystis neurona* in horses. Claim 29 has been amended to clarify that two sets of antibodies are being produced, so as to supply an antecedent basis for the antibodies to the 16 (+/-4) kDa antigen and antibodies to the 30 kDa (+/-4) antigen in step (e). Reconsideration of the rejection is requested.

35 U.S.C. §112, First Paragraph

A. Claim 29 was rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time that the application was filed, had possession of the claimed invention.

According to M.P.E.P. 2163, possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. *See, e.g., Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406; *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it").

An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention. *See, e.g., Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000) (the written description "inquiry is a factual one and must be assessed on a case-by-case basis"); *see also Pfaff v. Wells Electronics, Inc.*, 55 U.S. at 66, 119 S.Ct. at 311, 48 USPQ2d at 1646 ("The word 'invention' must refer to a concept that is complete, rather than merely one that is 'substantially complete.' It is true that reduction to practice ordinarily provides the best evidence that an invention is complete. But just because reduction to practice is sufficient evidence of completion, it does not follow that proof of reduction to practice is necessary in every case."). Reconsideration of the rejection is requested.

B. Claim 29 was rejected under 35 U.S.C. §112, first paragraph, as containing subject which was not described in the specification in such a way as to enable one skilled in

the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

According to M.P.E.P. 2164.02, the lack of working examples should never be the sole reason for rejecting the claimed invention on the grounds of lack of enablement. An applicant need not have actually reduced the invention to practice prior to filing. Compliance with the enablement requirement of 35 U.S.C. §112, first paragraph, does not turn on whether a working example is disclosed. The specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. *In re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970). There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

(A) The breadth of the claims;

(B) The nature of the invention;

(C) The state of the prior art;

(D) The level of one of ordinary skill;

(E) The level of predictability in the art;

(F) The amount of direction provided by the inventor;

(G) The existence of working examples; and

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). The examiner's analysis must consider all the evidence related to each of these factors, and any conclusion of nonenablement must be based on the evidence as a whole. 858 F.2d at 737, 740, 8 USPQ2d at 1404, 1407. Detailed procedures for making and using the invention may not be necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention (M.P.E.P. §2164).

According to M.P.E.P. 2164.05(a), whether the specification would have been enabling as of the filing date involves consideration of the nature of the invention, the state of the prior art, and the level of skill in the art. The state of the prior art is what one skilled in the art would have known, at the time the application was filed,

about the subject matter to which the claimed invention pertains. Considering the state of the prior art relating to passive immunization, the amount of direction provided by the inventors to make the passive immunity vaccine, and the high level of one or ordinary skill in the art of vaccine production, the subject matter was described in the specification in such a way as to enable one skilled in the art to make the invention.

The quantity of experimentation needed to be performed by one skilled in the art is only one factor involved in determining whether "undue experimentation" is required to make and use the invention. "[A]n extended period of experimentation may not be undue if the skilled artisan is given sufficient direction or guidance." *In re Colianni*, 561 F.2d 220, 224, 195 USPQ 150, 153 (CCPA 1977). "The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (citing *In re Angstadt*, 537 F.2d 489, 502-04, 190 USPQ 214,

217-19 (CCPA 1976)). The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm"n 1983), *aff'd. sub nom., Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985). See also *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. While the cited references suggest that some experimentation may be necessary to make the passive vaccine, the test of enablement is not whether any experimentation is necessary, but whether if experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976).

M.P.E.P. 2164.01(b) states, that as long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Applicants describe passive immunity vaccine production starting on page 26, line 27. Reconsideration of the

rejection is requested.

35 U.S.C. §103(a)

A. Claim 29 was rejected under 35 U.S.C. §103(a) as being unpatentable over Liang *et al.* 1998 (*Infection and Immunity;* 66(5) 1834-1838) in view of Harlow and Lane, (*Antibodies, A Laboratory Manual,* Cold Spring Harbor Press, 1988).

The four factual inquires enunciated by the Supreme Court in *Graham v. John Deere* as a background for determining obviousness are as follows:

(A) Determining the scope and contents of the prior art;

(B) Ascertaining the differences between the prior art and the claims in issue;

(C) Resolving the level of ordinary skill in the pertinent art; and

(D) Evaluating evidence of secondary considerations.

See M.P.E.P. 2141, I., citing *Graham v. John Deere,* 383 U.S. 1, 148 USPQ 459 (1966). M.P.E.P. 2141.02 explains that ascertaining the differences between the prior art and the claims at issue requires interpreting the claim language, and considering both the invention and the prior art

references as a whole. As further clarified by the Federal Circuit, basic considerations which apply to obviousness rejections include a requirement that the claimed invention must be considered as a whole; the references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination; and that the references must be viewed without the benefit of hindsight reasoning. *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986).

The Supreme Court has recently held that the teaching, suggestion, motivation (TSM) test when applied as a rigid and mandatory formula is incompatible with the Court's precedents. Nonetheless, according to the Court, the TSM test captures a helpful insight. *KSR Int'l Co. v. Teleflex Inc.*, No. 04-1350, slip op. at 14, 15 (U.S. April 30, 2007). The cited prior art references do not teach or suggest all of the limitations of the claimed method. The cited references would not suggest to a person of ordinary skill in the art the desirability of a method for producing a passive immunity vaccine in horses with isolated antibodies to the 16 (+/-4) kDa antigen and the 30 (+/-4) kDa antigen of *Sarcocystis neurona* together. In addition, a

prior art reference must be considered in its entirety, *i.e.*, as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). Therefore, it is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983). Liang *et al.* teaches away from a passive immunity vaccine with isolated antibodies to the 16 (+/-4) kDa antigen and the 30 (+/-4) kDa antigen of *Sarcocystis neurona* together.

Liang *et al.* teaches that serum and cerebrospinal fluid (CSF) from horses with a clinical diagnosis of a neurologic disorder resembling equine protozoal myeloencephalitis (EPM) reacted with combinations of Sn30, Sn16, Sn14, and Sn11 proteins from *Sarcocystis neurona* (*S neurona*) to form various band patterns on an immunoblot. The serum and CSF samples were grouped together by Liang *et al.* based upon the resulting band patterns. Liang *et al.* then teaches that *in vitro* neutralization assays against *Sarcocystis neurona* merozoites isolated from bovine turbinate cell culture revealed "significant differences in

inhibitory activities between the groups of serum and CSF samples with different immunoblot band patterns" (Liang *et al.*: page 1837, first full paragraph.) However, when Liang *et al.* correlated band patterns with inhibitory activities it was concluded that "no inhibitory activity correlating with antibody to Sn30 was noted." (Liang *et al.*: page 1836, first paragraph.) This can be clearly seen with sample N6 which recognizes the Sn30 protein of *Sarcocystis neurona*. (Liang *et al.*: Figure 2 on page 1836.) The teaching of Liang *et al.* therefore, would not show or suggest to a person of ordinary skill in the art that a passive immunity vaccine in horses with isolated antibodies to the 16 (+/-4) kDa antigen and the 30 (+/-4) kDa antigen of *Sarcocystis neurona* together should be pursued. A person of ordinary skill in the art would not be motivated to pursue the claimed method for producing the passive immunity vaccine after reading Liang *et al.* Liang *et al.* would actually lead a person of ordinary skill in the art away from the claimed invention, since *in vitro* neutralization assays against *Sarcocystis neurona* merozoites show that the Sn30 antigen provides no inhibitory activity.

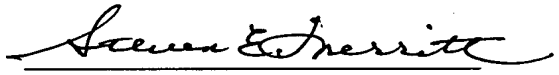
Harlow and Lane does not add anything to the

teachings of Liang *et al.* which would lead a person of ordinary skill in the art to the claimed invention. Neither Liang *et al.* or Harlow and Lane, either taken alone or in combination, would suggest to a person of ordinary skill in the art a method which provides isolated antibodies as a passive immunity vaccine against *Sarcocystis neurona* in horses. Neither reference even suggests a method for producing a passive immunity vaccine against the apicomplexan parasite *Sarcocystis neurona*. Liang *et al.* and Harlow and Lane, either taken alone or in combination, would not show or suggest to a person of ordinary skill in the art a method which provides isolated antibodies against the 16 and 30 kDa antigen together as the passive immunity vaccine in horses. Liang *et al.* actually teaches away from a method for producing a passive immunity vaccine which provides isolated antibodies against the 16 and 30 kDa antigen together. Therefore, the cited references would not lead a person of ordinary skill in the art to the claimed method. Reconsideration of the rejection is requested.

Conclusion

As shown above, the claimed method is not obvious over the cited prior art references and is supported by the specification. Therefore, Claim 29 is patentable. Reconsideration of the rejection is requested.

Respectfully,



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